

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

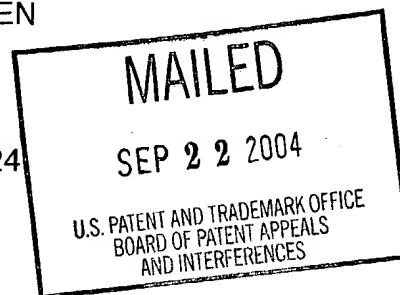
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte SARA L. ZAKNOEN

Appeal No. 2004-1974
Application No. 09/767,424

ON BRIEF



Before WILLIAM F. SMITH, SCHEINER, and MILLS, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-26, all the claims pending in the application.

Claim 1 is representative of the subject matter on appeal and reads as follows:

1. A method for treating a human patient afflicted with cancer, comprising administering therapeutically effective amounts of temozolomide and pegylated interferon alpha to such a patient.

The references relied upon by the examiner are:

Ragab
Kline

6,346,524 B1
6,180,096 B1

Feb. 12, 2002
Jan. 30, 2001

Gilbert et al. (Gilbert) (PCT Application)	WO 95/13090	May 18, 1995
Dugan et al. (Dugan) (PCT Application)	WO 97/12630	Apr. 10, 1997

Claims 1-22 stand rejected under 35 U.S.C. § 103(a). The examiner relies upon Dugan, Ragab, Kline, and Gilbert as evidence of obviousness. We affirm.

Discussion

We initially note that appellant states that the claims stand or fall together. Appeal Brief, page 4. Accordingly, we shall limit our consideration of the issues raised in this appeal as they pertain to claim 1. 37 CFR § 1.192(c)(7).

Claim 1 is directed to a method for treating a human patient afflicted with cancer. To this end, therapeutically effective amounts of temozolomide and pegylated interferon alpha are administered to such a patient.

The examiner has correctly determined that Dugan describes a method for treating a human patient afflicted with cancer by administering therapeutically effective amounts of temozolomide and interferon alpha. The sole difference between the method required by claim 1 on appeal and the method described by Dugan is the present requirement that the interferon alpha be "pegylated." Thus, the issue becomes would it have been obvious to a person of ordinary skill in the art at the time of this invention to use pegylated interferon alpha as the interferon alpha used in Dugan? We answer this question in the affirmative.

Gilbert states that pegylated interferon alphas are highly active, long lasting and provide predictable, uniform activity. Furthermore, Kline states that pegylated interferon alphas are useful in treating renal cell carcinoma and AIDS-related Kaposi's sarcoma. Id., column 6, lines 8-16.

We agree with the examiner's conclusion that a person of ordinary skill in the art would have found it obvious to use pegylated interferon alpha as the interferon alpha used in combination with temozolomide in Dugan. The motivation for using pegylated interferon alphanous matter is provided by Gilbert's disclosure that pegylated interferon alphas are highly active, long lasting and provide predictable, uniform activity as well as Kline's disclosure that pegylated interferon alphas have been used to treat cancer.

We have considered the arguments made by appellant in the Appeal Brief and Reply Brief but do not find them persuasive. Appellant argues that the references relied upon by the examiner do not contain "any teaching or suggestion to combine any of them in order to teach the appellant's claimed invention." Appeal Brief, pages 6-7. We disagree. As set forth above, Gilbert and Kline set forth the advantages which accrue from using pegylated interferon alpha instead of non-pegylated interferon alpha. Thus, from a reading of the references together, a person of ordinary skill in the art would have understood at the time of the present invention that advantages accrue from using pegylated interferon alpha in methods that previously used non-pegylated interferon alpha such as the method described in Dugan.

Appellant also argues that the claimed method has a "synergistic advantage." Appeal Brief, page 7. In support of this argument, appellant refers to "the detailed clinical study design as described in the specification from pages 8 to 23." Id. The clinical study design referenced by appellant is just that, a design. The studies outlined on pages 8-23 of the specification are prophetic in nature and do not appear to represent work that has actually been performed. Thus, it is not apparent how appellant can state that the "claimed method has a synergistic advantage." On this record, such statements are unsupported by any objective evidence of nonobviousness.

Appellant next argues that the applied references do not contain the proper motivation to render the present invention obvious. Appeal Brief, pages 7-8. We disagree. Gilbert and Kline provide ample motivation to combine the references in the manner required to arrive at the subject matter of claim 1 as a whole.

Appellant next characterizes the examiner's rejection as "obvious to try." Appeal Brief, pages 8-9. Appellant again relies to the proposed clinical study design set forth on pages 8-23 of the specification. It cannot be gainsaid that the prior art clearly describes the use of temozolomide and interferon alpha together to treat cancer. Nor can it be denied that the prior art describes pegylated interferon alpha along with its advantages over non-pegylated interferon alpha. Thus, the evidence of obviousness relied upon by the examiner amply supports the conclusion that those of ordinary skill in the art at the time of the present invention understood that temozolomide, pegylated interferon alpha and non-pegylated interferon alpha were known to be useful in treating cancer. There is substantial evidence supporting the examiner's conclusion of

obviousness. We remind appellant that a conclusion of obviousness does not require absolute predictability, only a reasonable expectation of success. In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) and In re Longi, 759 F.2d 887, 897, 225 USPQ2d 645, 652 (Fed. Cir. 1985).

Finally, appellant urges that the examiner has engaged in impermissible hindsight in combining the references in order to arrive at the subject matter of claim 1. We disagree. As explained above, the references provide ample motivation to support the examiner's proposed combination. We note that appellant again urges that the present method results in synergism. Appeal Brief, page 10 ("[T]here is no teaching in any of the cited references that temozolomide and pegylated interferon- α can be synergistically combined.") However, as previously noted, appellant has not relied upon objective evidence of non-obviousness in support of these assertions.

We have reviewed the arguments set forth in the Reply Brief and find that they are in essence those made in the Appeal Brief and do not convince us of any error in the examiner's position. The decision of the examiner is affirmed.

AFFIRMED

INTERFERENCES

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